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(54) **A mammary prosthesis**

(57) A mammary prosthesis comprises a flexible backing element and a soft front envelope. Within the flexible backing element there is at least one internal passageway or compartment into which a settable reinforcing filling material can be introduced. Upon setting of the reinforcing filling material in the passageways or compartments, the backing element loses a substantial part, if not all, of its flexibility. The reinforced backing element then prevents the contraction of natural fibrous tissues which normally takes place around the front envelope after implantation, so as to prevent hardening of the prosthesis and/or to avoid palpable prosthesis edges.

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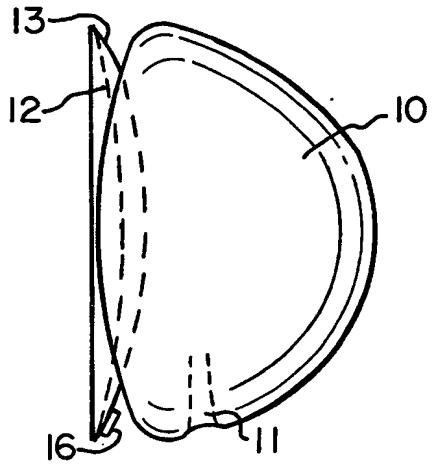


Fig. 1

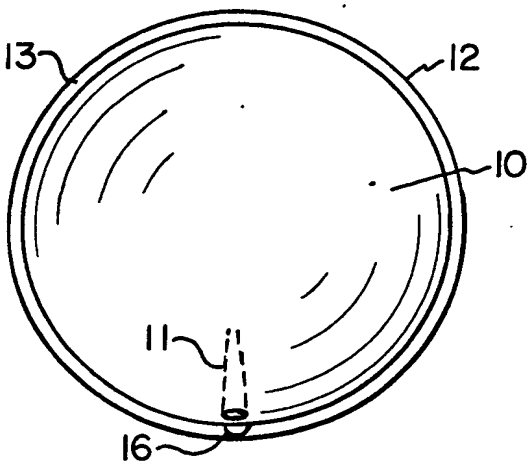


Fig. 2

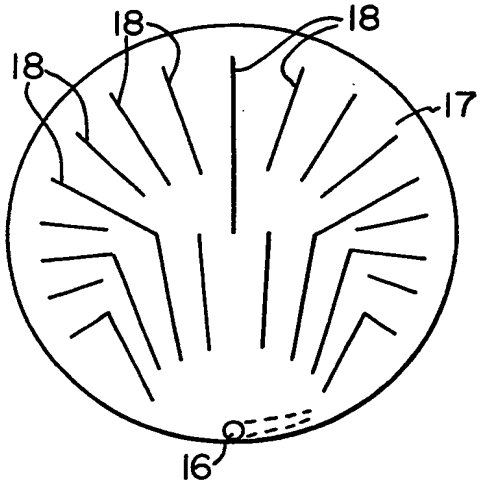


Fig. 3

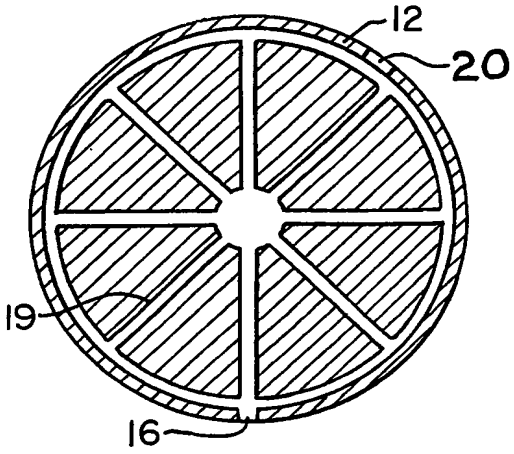


Fig. 4

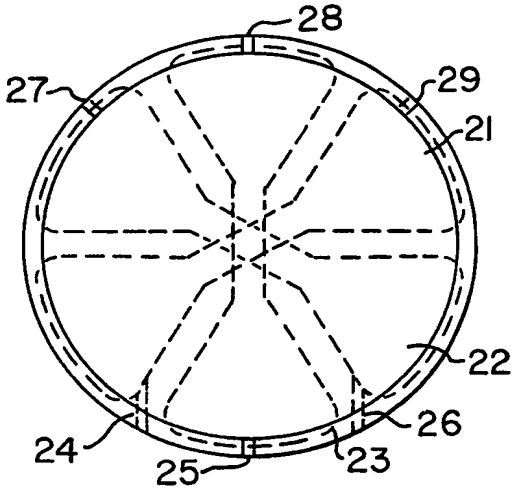


Fig. 5

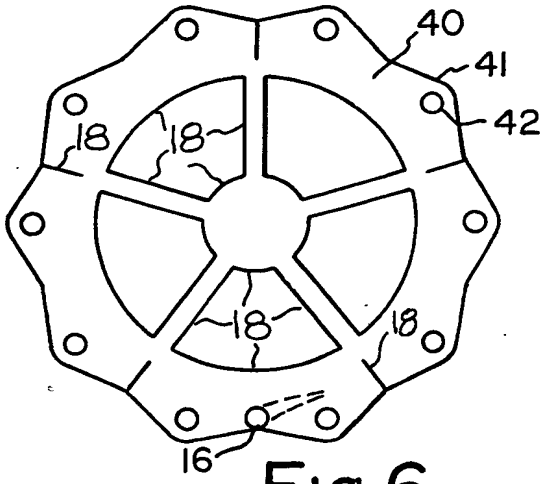


Fig. 6

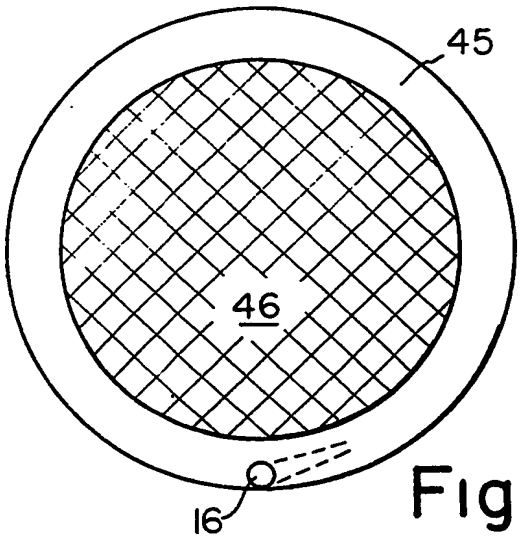


Fig. 7

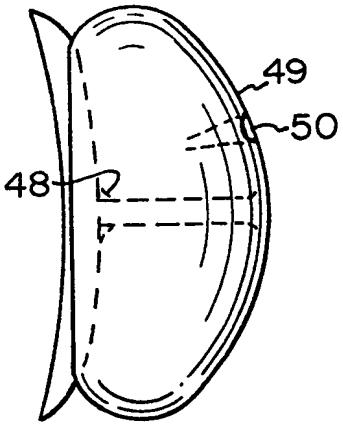


Fig.8

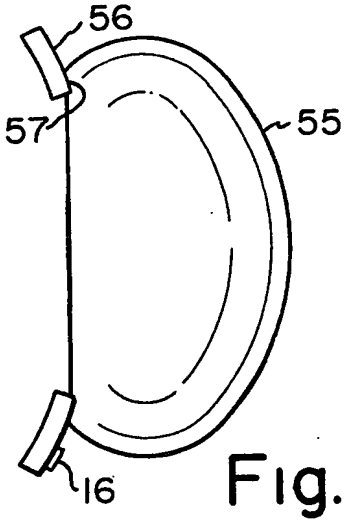


Fig.9

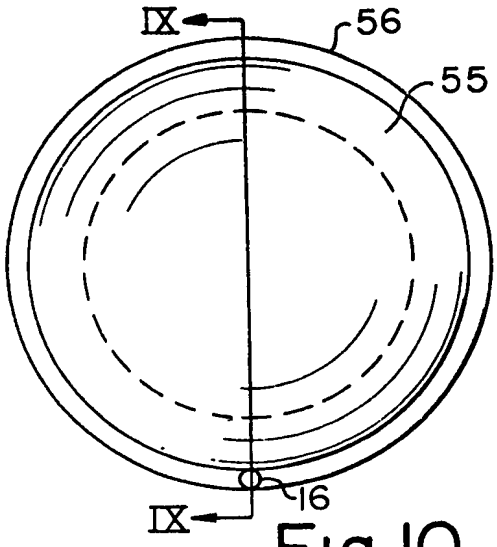


Fig.10

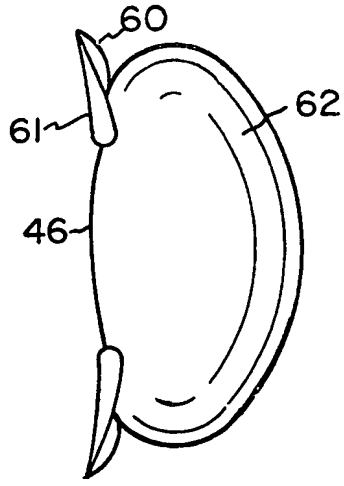


Fig.11

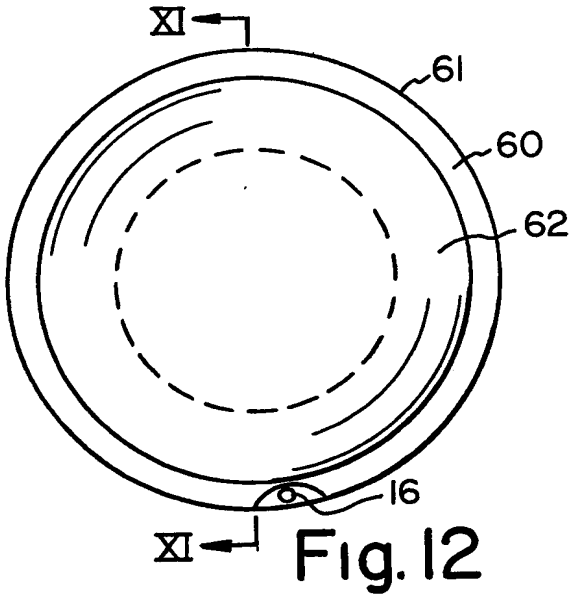


Fig. 12

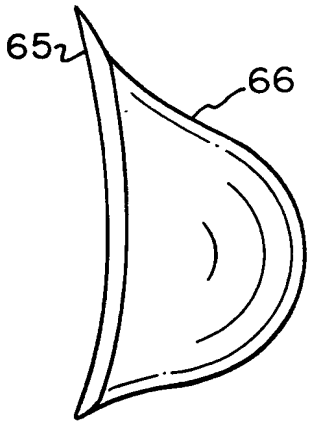


Fig. 13

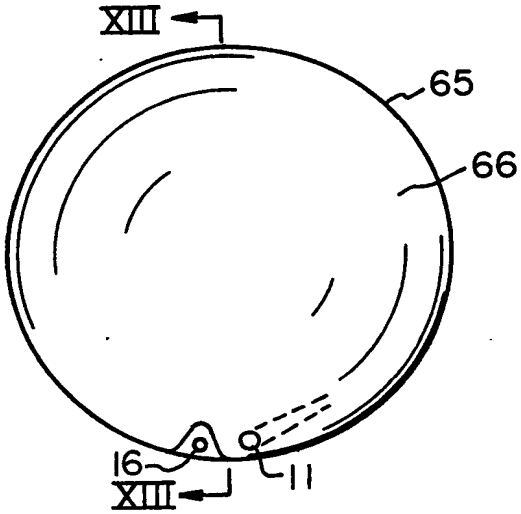


Fig. 14

SPECIFICATION

**A mammary prosthesis**

The present invention relates to a mammary prosthesis.

Mammary prostheses are known, and have been employed both to increase breast size (augmentation) and to restore the breast mound in reconstruction procedures following mastectomy. The known prostheses typically comprise an outer shell or envelope of thin silicone elasomer, and are either prefilled with a silicone elastomer 'gel' or are filled with a saline solution through a tube and valve after implantation. Prostheses are available in numerous sizes (volumes), and several shapes including tear drop, round and low profile. Some known prostheses have Dacron patches on the back to allow subsequent fibrous tissue ingrowth thereby causing the prostheses to be adherent to the chest wall or pectoralis muscle. Usually prostheses are implanted via a small inframammary or peri-aerolar incision into a pocket dissected deep into the patient's own breast tissue in front of the pectoralis muscle. In certain circumstances, such as reconstruction after mastectomy, the prosthesis may even be placed behing the pectoralis musle.

Whatever implanatation technique is used, the prosthesis is surrounded by a natural 'capsule' composes of fibrous scar tissue after it has been implanted for some period of time. This is a normal tissue reaction to the presence of a foreign body. Scar tissue normally undergoes contraction during the healing process. This capsule of scar tissue contracts to different degrees in different patients, and tends to deform the prosthesis towards a spherical shape in which the ratio between the capsule surface area and the volume of the breast prosthesis is minimised. The contraction of the capsule may be slight, so that the breast still feels soft and natural when examined, or it may so compress the silicone elastomer gel or saline contents of the prosthesis that the breast will feel quite hard and unnatural when examined. The point where any given augmented breast falls on the spectrum from soft to hard depends upon the patient's own scar contraction process. It has been reported that flexible silicone backings placed behind the soft front envelope result in a softer breast mound. However, since the backings were not rigid, they tended to curl up against the front envelope under the action of the scar capsule contraction when placed in the usual location over the pectoralis muscle. This is discussed, for example, by Rybka and Cocke in 'The Value of Silicone Dacron-Felt Discs in Prevention of Capsular Contractions' *Plastic Surgical Forum, Vol. 1 p. 221 (1978).*

A basic requirement of any mammary prosthesis is that it can be inserted through a three to four centrimeter incision. Hence, the backing must not be rigid prior to implantation in a pocket behind the breast. Further, the edges of the backing of the implant must not be palpable. A backing member must contour itself to the chest wall and/or the pectoralis muscle over which it is laid so that it does not rock back and forth. In addition it is essential that the prosthesis should not interfere with chest X-rays and mammography.

Two patents which relate to mammary prostheses are U.S. Patents Nos. 3,293,663 and 3,934,274.

According to the present invention, there is provided a mammary prosthesis comprising a front envelope of biologically inert elastomer filled or fillable with biologically inert fluid or gel, and a flexible backing element of a biologically inert material, the backing element having at least one enclosed volume therein, for receiving a settable reinforcing material.

The terms 'biologically inert' or 'inert' as used herein will be understood to refer to a material which is compatible with human body tissues in that it does not react with such tissue, nor provoke a reaction therein.

The reinforcing material is one able to set or harden and the backing element is thus reinforced to resist warping or buckling. The terms 'set' or 'harden' as used herein will be understood to relate to a state of material in which it is able at least substantially to resist an applied deforming force. Complete rigidity is not essential. The reinforcing filler material must be harmles and inert to tissue in case it should leak during the filling process or become exposed by a later tear in the prosthesis. Preferably, the front envelope is fixed to the said backing element although this is not an absolute requirement.

Implanting a prosthesis according to this invention involves only established surgical techniques. Either an inframammary or a peri-aerolar incision is made and the prosthesis described hereinabove is worked into position either against the chest wall or over the pectoralis muscle. Before or after the prosthesis has been inserted and positioned to the surgeon's satisfaction, a settable material, for example, a methyl methacrylate bone cement is forced into the enclosed volume within the flexible backing element, through at least one port provided for this purpose.

The enclosed volume of the backing element may alternatively be prefilled, in which case this filling step is eliminated. However, in this case, setting of the reinforcing material must be initiated, either just before the prosthesis is inserted, or after it has been inserted. Setting may be activated, for example, by exposure to ultraviolet light, although other means may be employed. Typically, cements take about ten minutes to harden or set. The flexible backing with the unset cement therein may be shaped by kneading to correspond to the chest or, at least, urged into a spheroidal shape having the concave portion thereof facing the chest. The molded backing is restrained by hand pressure or otherwise until the reinforcing material has set. Thereafter, if the front envelope portion of the prosthesis is not a prefilled envelope or was not already inflated in place, the front envelope is inflated through a port provided for this purpose.

The ratio between the surface area of the scar capsule and the volume of the breast prosthesis is increased in relation to that obtained using previously known prostheses for several reasons. Principally,

the invention provides a rigid backing to the breast mound portion of the prosthesis (referred to herein as the front envelope) which thus reduces the amount of possible contraction thereof towards the spherical shape. The ratio between the surface area and the volume of the breast prosthesis can be further increased by employing a backing element having a spherical shell configuration with the concave portion facing toward the chest. Alternatively a flat backing element can be kneaded to adopt this shape during the setting time of the reinforcing material, as discussed above.

In one embodiment the enclosed volume in the backing element comprises at least an annular passage way near the outer edge of the backing element. In another embodiment the enclosed volume in the backing element comprises or includes radially extending passageways therein.

An embodiment of particular interest has a backing element which extends radially outwardly of the front envelope, in the form of a collar. This collar must be relatively stiff so that the scar tissue contraction process will not pull it up onto the front envelope portion of the prosthesis and thereby negate its effect in increasing the surface area of the capsule. This particular embodiment might not be used with a very thin patient with minimal subcutaneous tissues as edges of the collar might be palpable. The collar provides a space into which the front envelope of the prosthesis may flow when the patient moves or changes position whereby to provide a more natural appearance.

The backing element in an alternative embodiment is annular, has at least one passage therein, and has an inelastic flexible centre portion. In embodiments intended to be filled after implantation the enclosed volume in the backing element may have at least one air bleed outlet, although this would not be necessary if the backing element is so formed that the enclosed volume can be completely evacuated, for example by being made of resilient or flexible flat sheets of material.

The backing element may have serrated edges, and whether or not the edges are serrated a plurality of tissue ingrowth apertures may be provided adjacent the periphery of the backing element.

In one embodiment the backing element has a plurality of separate enclosed volumes therein, each having an associated port for the introduction of settable reinforcing material, the arrangement of the said plurality of enclosed volumes being such that when a reinforcing material has been introduced and set they form separate panels which can be flexed with respect to one another. Preferably the panels formed upon filling of the said plurality of separate enclosed volumes overlaps one another.

It may be convenient if the said port for introducing material into the backing element extends through the front envelope.

In another embodiment the backing element is annular and the front envelope is attached thereto at or adjacent the inner annular edge thereof, and the back surface of the front envelope is reinforced with an inelastic flexible material.

For added naturalness the backing element may have a flexible annular envelope attached at or adjacent the outer edge of the front face thereof. This softens the outline of the prosthesis when implanted, and helps to conceal the edge thereof.

Another embodiment of the invention is shaped to provide a concealed edge. In this embodiment the front envelope is so shaped at the outer edges thereof that it is substantially tangential to the flexible backing element over a part of the outer edge thereof.

The backing element may be shaped to face or contact the entire back surface of the front envelope or alternatively to face or contact less than the entire back surface, for example the lower half of the back surface of the front envelope.

The backing element may extend radially outwardly of the front envelope along the lower half of the back surface of the front envelope.

A further embodiment of the invention has a backing element which comprises an envelope of flexible elastomer having two major faces joined at the periphery thereof and having a plurality of elongate quilt-like joins between the faces. Other embodiments are envasaged in which the backing element comprises a flexible plastics material disc having a network of passageways therein defining the said enclosed volume.

The invention is illustrated, merely by way of example, in the accompanying drawings, in which:

*Figure 1* is a side view of a prosthesis formed as one embodiment of this invention;

*Figure 2* is a front view of the prosthesis shown in Figure 1;

*Figure 3* is a front view of a flexible backing element in the form of a thin flat envelope of flexible elastomer suitable for use in an embodiment of the invention;

*Figure 4* is a cross sectioned front view of a different flexible backing element suitable for use in an embodiment of the present invention;

*Figure 5* is a front view of a flexible backing element, suitable for use in an embodiment of this invention, having three separate compartments;

*Figure 6* is a front view of another backing element suitable for use in an embodiment of this invention, having serrated edges and holes in the edges for tissue ingrowth;

*Figure 7* is a front view of a backing element suitable for use in an embodiment of this invention, and comprising an annular member the central area of which is covered with an inelastic cloth;

*Figure 8* is a side view of a preferred embodiment of this invention, in which a port for injecting reinforcing material into passageways in the backing element is accessible through the soft envelope.

*Figures 9* and *10* are, respectively, lateral and frontal sections of an embodiment of the invention having a flexible backing element in the shape of an annular member with a spheroidal surface;

*Figures 11* and *12* are, respectively, lateral and frontal sections of a prosthesis formed as an embodiment of this invention, in which the flexible backing element is an annular disc having a second, soft envelope positioned around the periphery of the front face thereof; and

*Figures 13* and *14* are, respectively lateral and frontal sections of a prosthesis formed as an embodiment of this invention, in which the front envelope thereof is approximately tangential to the flexible backing element over a part of the outer periphery thereof.

Referring now to Figures 1 and 2, there is shown a mammary prosthesis according to this invention, comprising a front envelope 10 which is made of a silicone elastomer for other suitable material, and may be prefilled, for example with a silicone gel, or provided with a valve such as that schematically shown as 11 so that it may be inflated with a saline solution or other suitable material, after having been implanted, as is the common practice. The front envelope 10 has a flexible backing element 12 in the form of a thin disc. In this embodiment the disc is of slightly greater outer dimension than the front envelope 10 thus providing a collar or flange 13 surrounding the front envelope. The shape and outer dimensions of the backing element may be different, however, and may, for example, be round with a diameter from 7 to 20 centimeters. Other shapes having curved edges, for example parabolic or oval are suitable. The flexible backing element is made of a silicone plastics material, an elastomer or other material which is not biologically reactive with the human body. The flexible backing element must, however, have sufficient inherent stiffness that as the reinforcing material is being forced into the passageways and/or compartments thereof it does not bulge and deform and thus impede flow into the interior passageways and compartments.

The backing element 12 forms a part of a spherical shell having a concave portion which faces toward the chest wall after implantation and away from the front envelope 10 of the implant. This prevents rocking and makes the edges less palpable.

Figure 3 illustrates a part of another embodiment of this invention, in which the flexible backing element may be made of an elastic material, for example the same material as that from which the front envelope of the embodiment is made or some very similar material. This material, for example a silicone elastomer, is formed into a thin wall envelope 17 the walls of which are typically in the region of 1 mm. thick, this envelope 17 having a plurality of elongate joins 18 between front and back walls thereof as does a quilt although, of course, without switching. The joins 18 are formed by welding, bonding, or the like. Preferably, the joins 18 do not extend entirely to the periphery of the envelope thus enabling an uninterrupted ring of reinforcing material to extend around the periphery of the backing element. At least one inlet port 16 is provided, together with suitable air bleed outlets (not shown) if desired. In the embodiment of Figure 3 air bleed outlets are not necessary as the enclosure 17 may be completely evacuated prior to filling with a reinforcing material.

In all of the disclosed embodiments, but especially the embodiment of Figure 3, the volume of reinforcing material contained by the compartments and/or passageways within the envelope constituted by the backing element must not be more than that needed to reinforce the backing element. Otherwise, the heat of reaction of the reinforcing material as it sets may deform the backing element and/or burn the patient. The passageways or compartments in the backing element enclosure should provide a large surface-to-volume ratio (that is, it should be thin) to minimise the amount of heat which can be transferred to any given area of adjacent body tissue. It is desirable that at least one side of the backing element be made of a fabric reinforced to prevent stretching of that side during the time when the reinforcing filler is being added.

With reference to Figure 4, there is shown another embodiment in which the backing element 12 is made of a flexible plastics material. The flexible plastics backing element 12 has internal radial passageways 19 therein, together with an inlet port 16 and at least one air bleed outlet 20. The thickness of the backing element may lie between about 2 and about 15 millimeters, with the passageways 19 being preferably at least 2 millimeters across. The backing element is reinforced after implanting, by forcing a settable material into the passageways 19 through the port 16. The air bleed outlet 20 allows for the escape of air which would otherwise be entrapped in the passageways 19. The position the ports 16 and 20 at the peripheral edge of the backing is acceptable for use in implanting techniques involving an inframammary incision. The diameter of the air bleed outlet 20 is such that the viscosity of the reinforcing material prevents it from escaping through this outlet (or plurality of outlets if more than one is provided). The inlet port 16 leading to the passageways is suitably the same diameter as the passageways and may be slightly tapered outwardly to receive a funnel shaped tube or the like through which the reinforcing material can be forced into the passageways of the backing element. Although not shown as such the port 20 may be designed for a bayonet connection with the tube through which the reinforcing material is to be injected, and this construction is preferred. It may be desirable in this, and in the other embodiments, to provide a check valve in the inlet port 16 to permit the inflow of material but not the outflow thereof. After setting, the reinforcing filler material has no tendency to flow out of the backing element and hence there is no need to provide a valve for this purpose. However, care must be taken to ensure, at least temporarily, that the port is plugged after filling and before setting of the material has taken place if the pressure exerted on the backing element to cause it to conform to the shape of the chest would be likely to cause extrusion of the reinforcing material out of the port. The flexible plastics material backing element may be fabricated from two or more thin flexible (but not elastic) plastics sheets of, for example, from 2 to 7 millimeters thick, with the passageways routed out of one surface. The sheets are then welded, bonded, glues or otherwise secured together in a manner such as to create passageways which are only accessible from the inlet port 16.

Referring now to Figure 5, there is shown a variation of the embodiment illustrated in Figures 1 to 4 in which the flexible backing element is provided

with three separate compartments 21, 22, and 23 each having its own inlet port 24, 26, and 25 respectively and each having its own air bleed outlet 29, 27, and 28 respectively. The three compartments which, when filled, create three rigid panels, are not interconnected. The backing element of this embodiment provides a limited amount of flexibility in the backing but in such a way as to prevent the warping or collapse of the backing element and curling of the edges. The backing element of this embodiment may be made from four thin plastics material sheets which are routed out to define the compartments before bonding together.

With either the backing element described with reference to Figure 3, which is made of an elastic material, or the backing element described with reference to Figure 4, which is made of an inelastic flexible plastics material, it is essential that the reinforcing material should extend sufficiently near to the peripheral edge of the element to prevent warping and curling of that edge.

Referring now to Figure 6, there is shown a backing element 40 of the elastic envelope type, having a serrated peripheral edge 41 and spaced tissue ingrowth apertures 42 adjacent the periphery. The serrated edges and/or the ingrowth apertures provide for a better blend of the edges of the flexible backing element into the chest wall or the pectoralis muscle. In this way it is less likely to be palpable through the skin and subsutaneous tissues. The edges of the backing element may be tapered somewhat to reduce palpability; however, it is essential that the backing element should not be so tapered that after the reinforcing filler material has been injected therein, it may still be warped and curled at the edges thereof. It may be desirable to provide fabric, such as Dacron, or other tissue ingrowth patches on the front and/or the back of the backing element in order to promote blending of the backing element with the surrounding tissue and to prevent it from shifting relative to the chest wall and/or the pectoralis muscle and/or the overlying skin flaps.

Referring to Figure 7, there is shown a backing element 45 which has annular configuration. The inner edge of the annular element 45 is secured to inelastic cloth 46 or a cloth reinforced silicone elastomer or the like. This has the advantage of additional flexibility and ease of contouring to the chest wall. The cloth 46 prevents the front envelope from working through the central opening of the annulus. Thus, the collar 45 does not move up along the front envelope.

Referring now to Figure 8, there is shown an embodiment of this invention in which a port 48 for injecting reinforcing material into the passageways in the backing element is located centrally of the backing element and is accessible through a passageway in a front envelope 49. This particular embodiment is useful for implants which are to be installed through a peri-aerolar incision and the front envelope 49 is of the inflatable type. The valve 50 for inflating the front envelope 49 is provided centrally of the envelope as shown in the drawing. The detal of valves for filling the inflatable envelopes has not been described as these are known in the art.

Referring to Figures 9 and 10, there is shown a further embodiment in which a front envelope 55 is secured to an annular rigid backing element 56 at a location 57 near the inner annular edge thereof. The front envelope 55 has a cloth reinforced backing.

In Figures 11 and 12, there is illustrated an embodiment of this invention wherein the backing element, indicated 61, has a second front envelope 60 attached to the outer annular surface thereof. The second front envelope 60 is a prefilled annular envelope and the primary front envelope 62 rests within the space circumscribed by the annular second front envelope 60. The purpose of the second front envelope 60 is to reduce the palpability of the radially outer edges of the annular backing element 61.

Referring now to Figures 13 and 14, there is illustrated an embodiment of this invention wherein the front envelope of the prosthesis, indicated 66, is secured to the backing element 65 and the edge of the front envelope 66 is tapered in such a way that the surface of the front envelope 66 is substantially tangential to the backing element at the outer edges thereof. This configuration is designed to minimize the palpability of the edges of the reinforced backing element.

While it is desirable to have the front envelope attached to the flexible backing element, this is not absolutely necessary as after installation they will in any case cooperate together to prevent the spherical contraction which results in many cases of mammary prosthesis implantation.

If it should become necessary to remove the implant at a later date, it will be necessary to cut the reinforced backing element into strips or the like to facilitate removal. Thus the reinforcing material must be one which is capable of being cut with, for example, a surgeon's common bone roungers. It is considered that methyl methacrylate bone cement will be suitable as the reinforcing filler material so long as its tendency to heat-up during curing is taken carefully into consideration in determining quantities and dimensions. One cement that would be a suitable filler material is sold under the trademark 'Cranioplastic' by the L.D. Cauble Company, and consists of a powdered portion comprising methyl methacrylate polymer, methyl methacrylatestyrene copolymer and very small amounts of benzoyl peroxide, and a liquid portion comprising methyl methacrylate monomer, ethylene dimethacrylate monomer and very small amounts of dimethyl p-toluidine and hydroquinon.

Another product of the type that could be used as a filler material is 'Surgical Simplex P Radiopaque' bone cement sold by Howmedica International Ltd. and is described as including methyl methacrylate, a mixture of polymethyl methacrylate, methyl methacrylate-styrene copolymer and barium sulfate. Yet another product that may be used as a filler material is room temperature vulcanizing (RTV) silicone rubber. There are also certain silicone gels which can be made to set hard by the application of heat.

Another material suitable for use as the reinforcing filler is a product sold by 3M Corporation under

the trade name 'Concise Enamel Bond Resin.) It comprises bisphenol-A glycidyl methacrylate, triethylene glycol dimethacrylate, methyl methacrylate, a catalyst and an accelerator.

It should be understood that the backing element could be prefilled with a settable filler material that can be caused to set by some external agency. For example, there are materials that are activated to set by exposure to ultraviolet light. Thus by means of an ultraviolet light source with which to irradiate the material through the backing walls, the filler may be activated to set and become effectively rigid. The setting process is not immediate upon irradiation but is simply initiated by irradiating a portion of the material. The irradiation with ultraviolet may take place just before the backing element is implanted, or after it has been implanted. It may only be necessary to irradiate a portion of the ultraviolet light sensitive filler material, following which the setting reaction will progress to all contiguous parts of the filler material. in this case, the backing element may be factory-filled, and the port through which the filler material was introduced can be permanently closed off at the factory.

Exemplary of the fillers setting of which may be initiated from outside the backing envelope by means of ultraviolet light are the following: A product sold under the trade name 'Nuva Seal' which comprises Bowen's Resin and benzoin methyl ether as an initiator which is activated by ultraviolet light. It has been found that ultraviolet light passes through the thin silicone walls of the breaking envelope in sufficient amounts to activate this resin.

There are also materials, for example silicones, which when subjected to heat and/or pressure, are activated to set and become rigid. The backing element could be prefilled with these materials and placed in an autoclave for activation immediately prior to being implanted.

Another technique for external activation of prefilled material within the backing element envelope is to provide an initiator or catalyst for the settable filler material in a compartment separated from that housing the remainder of the resin by an easily ruptured membrane. Prior to installation the prosthesis is manipulated to rupture the membrane and to disperse the initiator catalyst throughout the remainder of the filler.

It should be understood that the reinforcing material need not be in the form of fluids or plastic masses but may comprise granular materials. The use of granular material is more practical with factory-prefilled backing elements than with backings filled just before or after implantation.

Further, in the case of prefilled backing elements, these may comprise a flexible sheet or layer of a settable filler, which is laminated between sheets of flexible silicone and sealed at the edges in such a way as completely to enclose the sheet or layer of settable material. In other words, the flexible sheet of settable material which, for example, may be activated by ultraviolet light, pressure or heat, is sandwiched between layers of materials which are compatible with the human body, such as medical silicones. Of course, such a flexible sheet or layer as that described above will not need to be encapsulated and sealed in silicone if, for example, it is itself made from a silicone or other biologically inert material.

In use only a small incision in the patient's skin is required and the backing element can be molded to fit the shape of the chest wall. The backing element, after the reinforcing material has set, prevents the scar tissue contraction from pulling the soft portion of the implant into a hard part-spherical shape as has sometimes happened with previous implants of this type.

It will be understood that the term 'set' as used herein is used to indicate a state in which a material is substantially resistant to deforming forces. it is not intended that this should be entirely rigid since a small degree of resilience or elasticity will be acceptable in some cases.

## CLAIMS

1. A mammary prosthesis comprising a front envelope of biologically inert elastomer filled or fillable with a biologically inert fluid or gel, and a flexible backing element or a biologically inert material, the backing element having at least one enclosed volume therein, for receiving a settable reinforcing material.

2. A mammary prosthesis as claimed in Claim 1, in which the backing element has at least one port communicating with the said enclosed volume, through which a fluid or plastic material may be introduced into the enclosed volume.

3. A mammary prosthesis as claimed in Claim 1, in which the said enclosed volume in the backing element is filled with a settable filler material, the setting of which can be activated by action external of the enclosed volume.

4. A mammary prosthesis as claimed in any of Claims 1 to 3, in which the front envelope has a port opening thereinto, through which a suitable material can be introduced into the front envelope.

5. A mammary prosthesis as claimed in any of Claims 1 to 3, in which the front envelope is filled with a gel.

6. A mammary prosthesis as claimed in any preceding Claim, in which the front envelope and backing element are made from a biologically inert silicone material.

7. A mammary prosthesis as claimed in any of Claims 1 to 6, in which the enclosed volume in the backing element comprises at least an annular passageway near the outer edge of the backing element.

8. A mammary prosthesis as claimed in any of Claims 1 to 7, in which the enclosed volume in the backing element comprises or includes radially extending passageways therein.

9. A mammary prosthesis as claimed in any preceding Claim, in which the backing element extends radially outwardly of the front envelope.

10. A mammary prosthesis as claimed in any of Claims 1 to 7, in which the backing element is annular, has at least one passage therein, and has an inelastic flexible centre portion.

11. A mammary prosthesis as claimed in any of Claims 1 to 9, in which the backing element has a concave configuration the concave surface of which faces away from the front envelope.

12. A mammary prosthesis as claimed in Claim 2 or in any of Claims 4 to 11 when dependent thereon, in which the enclosed volume in the backing element is provided with at least one air bleed outlet.

13. A mammary prosthesis as claimed in any preceding Claim, in which the backing element has serrated edges.

14. A mammary prosthesis as claimed in any preceding Claim, wherein tissue ingrowth apertures are provided adjacent the periphery of the backing element.

15. A mammary prosthesis as claimed in any of Claims 1 to 6, in which the backing element has a plurality of separate enclosed volumes therein, each having an associated port for the introduction of a settable reinforcing material, the arrangement of the said plurality of enclosed volumes being such that when a reinforcing material has been introduced and set they form separate panels which can be flexed with respect to one another.

16. A mammary prosthesis as claimed in Claim 15, in which the panels formed upon filling of the said plurality of separate enclosed volumes overlap one another.

17. A mammary prosthesis as claimed in Claim 2 or any of Claims 3 to 14 when dependent thereon, in which the said port for introducing material into the backing element extends through the front envelope.

18. A mammary prosthesis as claimed in any of Claims 1 to 10, 12, 13 or 17, in which the backing element is annular and the front envelope is attached thereto at or adjacent the inner annular edge thereof, and in which the back surface of the front envelope is reinforced with an inelastic flexible material.

19. A mammary prosthesis as claimed in any preceding Claim, in which the backing element has a flexible annular envelope attached at or adjacent the outer edge of the front face thereof.

20. A mammary prosthesis as claimed in any of Claims 1 to 18, in which the front envelope is so shaped at the outer edges thereof that it is substantially tangential to the flexible backing element over a part of the outer edge thereof.

21. A mammary prosthesis as claimed in any of Claims 1 to 9, 11 to 17, 19 or 20, in which the backing element is shaped to contact the entire back surface of the front envelope.

22. A mammary prosthesis as claimed in any of Claims 1 to 20, wherein the backing element is shaped to contact the lower half of the back surface of the front envelope.

23. A mammary prosthesis as claimed in Claim 22, in which the backing element extends radially outwardly of the front envelope along the lower half of the back surface of the front envelope.

24. A mammary prosthesis as claimed in any of Claims 1 to 6, in which the backing element comprises an envelope of flexible elastomer having two major faces joined at the periphery thereof and having a plurality of elongate quilt-like joins between the faces.

25. A mammary prosthesis as claimed in any of Claims 1 to 6, in which the backing element comprises a flexible plastics material disc having a network of passageways therein defining the said enclosed volume.

26. A mammary prosthesis substantially as hereinbefore described with reference to Figures 1 and 2, or Figure 3, or Figure 4, or Figure 5, or Figure 6, or Figure 7 or Figure 8, or Figures 9 and 10, or Figures 11 and 12, or Figures 13 and 14 of the accompanying drawings.

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